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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/585,464	05/03/2007	Marsha A. Moses	C1285,70006US01	5882
23628 7590 05/14/2009 WOLF GREENFIELD & SACKS, P.C. 600 ATLANTIC AVENUE BOSTON, MA 02210-2206				
EXAMINER				
HARRIS, ALANA M				
ART UNIT		PAPER NUMBER		
1643				
MAIL DATE		DELIVERY MODE		
05/14/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/585,464

**Applicant(s)**

MOSES ET AL.

**Examiner**

Alana M. Harris, Ph.D.

**Art Unit**

1643

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 March 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 3, 4, 6, 7, 9-16 and 20-37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 4, 6, 7, 9-16 and 20-37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/06)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Response to Amendment and Arguments***

1. Claims 1, 3, 4, 6, 7, 9-16 and 20-37 are pending.  
Claims 2, 5, 8 and 17-19 have been cancelled.  
Claims 1, 3, 4 and 7 have been amended.  
Claims 20-37 have been added.  
Claims 1, 3, 4, 6, 7, 9-16 and 20-37 are examined on the merits.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Withdrawn Objection***

***Claim Objection***

3. The objection of claim 3 is withdrawn because a period has been added at the end of the sentence, see amendment submitted March 9, 2009.

***Withdrawn Grounds of Rejection***

***Claim Rejections - 35 USC § 102***

4. The rejection of claims 1, 4, 7 and 9-16 under 35 U.S.C. 102(b) as being anticipated by Iba et al. (Am J. Pathol. 154(5):1489-501, May 1999) is withdrawn in light of Applicants' amendments to independent claims 1, 4 and 7. Claims 2, 5 and 8 have been cancelled.

5. The rejection of claims 1, 4, 7 and 9-16 under 35 U.S.C. 102(a) as being anticipated by Le Pabic et al. (Hepatology 37: 1056-1066, published December 2003) is withdrawn in light of Applicants' amendments to independent claims 1, 4 and 7. Claims 2, 5 and 8 have been cancelled.

***Maintained and New Grounds of Rejection***

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. The rejection of claims 1, 3, 4, 6, 7, 9-16 and new claims 20-37 under 35 U.S.C. 102(e) as being anticipated by Berger et al./ U.S. Patent Application Publication number 2003/0148410 A1 (filed November 21, 2002) is maintained and made. Claims 2, 5 and 8 have been cancelled.

Applicants set forth the criteria for establishing a rejection under 102, see page 8. Applicants assert Berger has not shown that ADAM12 is a secreted protein that is detected in biological samples as claimed, see page 8. These arguments and points of view have been carefully considered, but found unpersuasive.

It was noted in the first action on the merits (FAOM) mailed October 7, 2008, page 4, section 6, the publication discloses methods for detecting and characterizing human colon cancers implementing assays determining the level of mRNA marker **or marker protein**, see page 10, sections 0111, 0113 and 0114; and sections 0276-0299 beginning on page 31. Table 1 lists all of the markers disclosed in the invention including ADAM 12, art known as a disintegrin and metalloproteinase domain 12 or meltrin alpha, see page 4, section 0060 and the table. The **ADAM 12 protein marker** can be detected blood fluids, stool, colon lavage fluids, lymph fluids and urine via an antibody which is labeled by several means, see page 3, section 0048; page 10, section 0114; and page 33, section 0300. Moreover, the ADAM 12 protein marker is the same as that listed in the claims. Applicants' assertion that the ADAM 12 protein disclosed is not the same as a secreted ADAM 12 protein is moot because that limitation regarding a particular type of ADAM 12 protein is not listed in the claims. The rejection is maintained and made for the reasons stated herein and of record in the FAOM.

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The rejection of claims 1, 3, 4, 6, 7, 9-16 and new claims 20-37 under 35 U.S.C. 103(a) as being unpatentable over Iba et al. (Am J. Pathol. 154(5):1489-501, May 1999), and further in view of Berger et al./ U.S. Patent Application Publication number 2003/0148410 A1 (filed November 21, 2002) is maintained and made. Claims 2, 5 and 8 have been cancelled.

Applicants reiterate the standard for a 103 rejection, see Remarks, page 8, last paragraph. Applicants assert neither the primary reference, Iba or the secondary reference, the patent application publication by Berger provide a reason or motivation for one of ordinary skill in the art to combine the references, see Remarks, page 9. Applicants argue the merits of Iba noting both forms of ADAM 12 were measured and "because ADAM12-L is membrane-bound, a skilled artist would not have any expectation of success in detecting ADAM12-L in the biological samples of the instant claims.", see Remarks, page 9. These arguments and points of view have been carefully considered, but found unpersuasive.

Applicants arguments address particular forms of ADAM 12 and are moot because the claims do not delineate any particular the protein. The facts are clear, Iba teaches "[t]he distribution of ADAM 12 in... 37 human carcinomas compared with the

normal counterpart tissue... investigated by immunohistochemistry", see page 1493, Results section. These tissue specimens are from human carcinomas comprising ductal breast carcinoma, adenocarcinoma of the colon and rectum, squamous cell carcinoma of the lung and adenocarcinoma of the stomach, see page 1490, Tissue samples...section. Adjacent nontumorous tissues were also investigated. "All 15 cases of breast carcinomas exhibited intense ADAM 12 immunoreactivity (Figure 1A) using several different antibodies, whereas in normal breast tissue, only a few scattered luminal cells of the ducts exhibited ADAM 12 immunoreactivity (Figure 1E)", see page 1493, Results section. Labeled monoclonal antibodies to human ADAM 12 were implemented in the immunohistochemistry assays, see page 1490, Antibodies and Immunohistochemistry...sections; and Figure 1 on page 1494. "Breast carcinoma tissue appeared to contain more ADAM 12-L transcript than normal breast tissue (Figure 1G)", see bridging sentence of columns 1 and 2 on page 1493. Iba does not teach the disclosed method, wherein a biological sample assayed for ADAM 12 is urine, blood or serum.

However, Berger teaches urine and blood fluids as a biological sample to test for the presence or absence of ADAM 12, see page 3, section 0048; and page 8, section 0069. Blood and sera are regarded by the Examiner as blood fluids, It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the teachings of both documents assay a plethora of biological samples for ADAM 12, particularly a urine sample, blood or serum. One of ordinary skill in the art would have been motivated to do so with a reasonable

expectation of success by teachings because the publication implemented the diagnostic assay using urine, blood fluids as a test sample and ADAM 12 is clearly and definitively associated with tumor cancer, see Berger, page 3, section 0048 and page 33, section 0300; and Iba, abstract. The rejection is maintained and made for reasons of record and set forth herein.

### ***Conclusion***

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is



(571)272-0831. The Examiner works a flexible schedule, however she can normally be reached between the hours of 7:30 am to 6:30 pm, with alternate Fridays off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Alana M. Harris, Ph.D.  
07 May 2009  
/Alana M. Harris, Ph.D./  
Primary Examiner, Art Unit 1643